DOW CORNING

8EHQ-0903-15419

MR 269398

September 8, 2003

03 SEP -9 AM 11:01

Document Control Office (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Room G-099
Attn: TSCA Section 8(e) Coordinator
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Contain NO CBI

Re: TSCA Section 8(e) Notification of Substantial Risk:
Skin Sensitization caused by Material Number 4019413 in the Guinea Pig, using the Buehler Test Method.

Dear Sir:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the Statement of Interpretation and Enforcement Policy (40 FR 11110, 16 March 1978), Dow Corning is submitting the following information concerning an ongoing study:

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Chemical Substance:

137866-54-7 1,1,3,3,-Tetramethyl-1-(2-(7-oxabicyclo(4.1.0)hepta-3-yl)ethyl) Disiloxane

3277-26-7 Tetramethyldisiloxane

Manufacturer:

Dow Corning Corporation
2200 West Salzburg Road
Midland, Michigan 48686-0994

Ongoing Study:

MATERIAL NUMBER 4019413, CONTACT HYPERSENSITIVITY IN ALBINO GUINEA PIGS, BUHLER TEST (WITH POSITIVE CONTROL)

Dow Corning Study Number: 9835-101

Summary:

On completion of the in-life phase of an ongoing skin sensitization study using the Buehler Test Method with Guinea Pigs, the preliminary results indicate that the test article has the potential to cause skin sensitization. This preliminary result is based on twenty of twenty test animals showing evidence of delayed contact hypersensitivity following exposure to the test article at 75% (weight/weight (w/w)) in corn oil at the challenge application (study day 29). The test article contains greater than 60% of 1,1,3,3,-Tetramethyl-1-(2-(7-oxabicyclo(4.1.0)hepta-3-yl)ethyl) Disiloxane with Tetramethyldisiloxane present at less than 1%.

Details:

An identical patching method and application time was used for the preliminary investigation, induction, and challenge phases. The fur of the guinea pigs was shaved with a fine clipper blade just prior to topical administration.

Prior to the start of the main study, a preliminary investigation was performed to identify (a) irritant test article concentrations suitable for the induction phase of the main study, and (b) a maximum non-irritant concentration suitable for the challenge phase. Four female animals were treated topically with material number 4019413 at 100%, 75%, 50%, and 25% (w/w) in corn oil. This consisted of a single test article treatment of 0.5 ml on a 25 mm Hill Top Chamber® for six hours. The Hill Top Chamber® was held in place by an elastic plaster and impervious adhesive tape.

The results from the preliminary investigation showed that material number 4019413 was non-irritating up to 75% (w/w) in corn oil. Therefore, the test article was applied at 100% (w/w) during the induction phase.

Twenty female animals of the test group were treated topically with material number 4019413 at 100% once a week (study days 1, 8 and 15) for a three-week induction phase. The ten irritation control animals were treated in the same manner as the test animals, but they were not exposed to the test article. The dermal reactions were observed and recorded 24 hours after the dressings were removed from both the test and irritation control animals. At this concentration, discrete/patchy erythema was noted. This concentration, however, was determined to be well tolerated by the test group animals.

On the day of challenge (study day 29), test and irritation control animals were treated topically with material number 4019413 at 75% (w/w) in corn oil. Patches were applied to the clipped left posterior quadrant of the side and back of the test and irritation control animals. The dermal reactions were observed and recorded 24 and 48 hours after patch removal.

Twenty and nineteen of twenty test animals at the 24 and 48-hour readings, respectively, showed evidence of delayed contact hypersensitivity (discrete/patchy to moderate/confluent erythema) following a challenge application of the test article at 75% (w/w) in corn oil. No skin reactions were observed in the irritation control animals. Thus, the test article was considered a sensitizer in guinea pigs.

Actions:

The findings from this study will be communicated to appropriate internal and external audiences including employees and customers. The Material Safety Data Sheet for this test article already warns for the potential of allergic skin reaction. Dow Corning will provide the Agency with a copy of the final report from this study when it is available.

If you have technical questions concerning this study, please contact Dr. Kathleen P. Plotzke, Director of Health and Environmental Sciences, at 989-496-8046. If you require further general information regarding this submission, please contact Michael E. Thelen, Manager of US EPA Regulatory Affairs, at 989-496-4168 or at the address provided herein.

Sincerely,

Laura L. Perkins, PhD
Director of Environment, Health and Safety
(989) 496-8568